UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D453161; **FILE SYMBOL/REG. No.**: 91960-1-Alt3; **PRODUCT NAME**: Bifenthrin Technical; **DECISION No.**: 551653; **PC Code(s)**: 128825; **ACTION CODE**: R351; **FOOD Use**: Yes

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATE: November 25, 2019

SUBJECT: Product Chemistry Review of "Bifenthrin Technical"

FROM: Dehui Duan, Chemist
Product Chemistry Team
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

12.2.2019 12.2.19

TO: Vanessa Emerson / Catherine Aubee, RM 03
IVB1 / RD (7505P)

REGISTRANT: GENSOURCE INC.

MRID Number(s): 50779702, 50869901 and 50869902

INTRODUCTION:

The registrant is seeking to add a new source of Bifenthrin Technical. The registrant has submitted a proposed alternate CSF #3 dated 05/28/2019, Group A and Group B chemistry data with MRID Nos. 50779702, 50869901 and 50869902. Two other alternate CSFs #2 and #4 were also submitted under another PRIA action (Decision #: 548608/ DP#: 451289) and they are currently under review. Per Agency's advice, the registrant submitted a revised alternate CSF #3 dated 11/27/2019 to change the nominal concentration and certified limits of an isomer.

The approved Basic CSF dated 02/03/2016 – Nominal concentration: 98.5% – [redacted]

The approved Alternate CSF #1 dated 02/03/2016 – Nominal concentration: 98.5% – [redacted]

The proposed Alternate CSF #2 dated 02/09/2019 – Nominal concentration: 98.37% – [redacted] – MRID#: 50779703 and 50779704.

The proposed Alternate CSF #3 dated 11/27/2019 – Nominal concentration: 98.28% – [redacted] – MRID#: 50869901 and 50869902.

The proposed Alternate CSF #4 dated 02/09/2019 – Nominal concentration: 98.50% – [redacted] – MRID#: 50779701 and 50779702.

CITAB has been asked to determine the acceptability of the product chemistry data and the proposed alternate CSF #3.

DP BARCODE No.: D453161; **FILE SYMBOL/REG. No.**: 91960-1-Alt3; **PRODUCT NAME**: Bifenthrin Technical; **DECISION No.**: 551653; **PC Code(s)**: 128825; **ACTION CODE**: R351; **FOOD Use**: Yes

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550: (product identity & composition)

The active ingredient was adequately described (MRID 50869901). The nominal concentration of the active ingredient (98.28%) is the same as the average derived from the five-batch preliminary analysis results (98.28 %, from Page 8 of 253 in the Confidential Attachment of MRID 50869902). It is comparable to that stated on the approved basic CSF (98.28 vs 98.5%). The information presented meets the data requirements for 40 CFR 158.320.

830.1600: (description of materials used to produce the product)

Safety Data Sheets (SDSs) of all the starting materials, and their specifications, quality control measures and suppliers were provided in MRID No 50869901. The information presented meets the data requirements for 40 CFR 158.325.

830.1620 (description of production process)

A detailed description of type of process, manufacturing steps, vessels and equipment, in process control analysis, flow charts, recycling procedure and Post-production clean out were included in MRID No. 50869901. The information presented meets the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities)

Potential impurities listed on the alternate CSF #3 were identified and quantified as part of the five-batch analysis (MRID 50869902). [redacted] detected at levels greater than 0.1%. The formation and identities of the impurities were fully discussed in MRID 50869901. The information presented meets the data requirements for 40 CFR 158.335.

830.1700 (preliminary analysis)

[redacted]

The information presented meets the data requirements for 40 CFR 158.345.

830.1750 (certified limits)

The proposed upper and lower certified limits for the active ingredient are within the range of the guideline OCSPP 830.1750 recommendation. The upper and lower certified limits of isomer were proposed based on the results of five-batch analysis. The information presented meets the data requirements for 40 CFR 158.350

830.1800 (enforcement analytical method)

The analytical method for quantifying the active ingredient in Bifenthrin Technical was HPLC with external standard calibration, which was validated for linearity, selectivity, recovery, repeatability and intermediate precision (MRID 50869902).

The methods for quantifying impurities [redacted] (MRID 50869902).

All methods are capable of determining whether an ingredient falls within its certified limits. The information presented meets the data requirements for 40 CFR 158.355.

2. Group B guidelines (physical-chemical properties):

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Granular solid with mild acidic odor	A	50779702
830.6314	Oxidation/reduction	Compatible with common oxidizing and reducing agents.	A	50779702
830.6315	Flammability	Product is not combustible.	A	Data Matrix
830.6316	Explodability	Product is not potentially explosive.	A	Data Matrix
830.7000	pH	5.6 (1% w/v) at 20 °C	A	50779702
830.7100	Viscosity	Solid. Not required.	A	Data Matrix
830.7300	Density (units)	1.2549 g/mL @ 20 °C	A	50779702
830.6317	Storage stability Or Accelerated storage stability	Product is stable when stored at 54 °C for 14 days.	A	50779702
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	No significant corrosion was observed on the aluminium, polyethylene (HDPE) or mild steel with PVF lining discs when in contact with Bifenthrin TGAI under the test conditions	A	50779702

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable; I = In progress

CONCLUSIONS:

The CITAB has reviewed the proposed alternate CSF #3 (dated 11/27/2019) and the supporting Group A and Group B data for Bifenthrin Technical and has concluded that:

1. The product chemistry Group A data submitted for guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.

2. [redacted] not a toxicological concern.

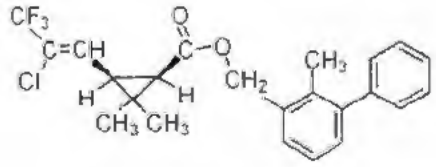
3. The product chemistry Group B data are acceptable.

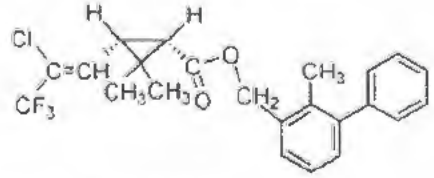
4. The proposed alternate CSF #3 (dated 11/27/2019) is acceptable.

Active Ingredient

Test substance:	**Bifenthrin TC**
Received in:	06/Jan/2015
Common name a.i.:	Bifenthrin
Chemical name (IUPAC) a.i:	2-methylbiphenyl-3-ylmethyl (*Z*)-(1*RS*,3*RS*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl cyclopropanecarboxylate
CAS number:	82657–04–3
Structural formula:	

(*Z*)-(1*R*)-*cis*-





(*Z*)-(1*S*)-*cis*-

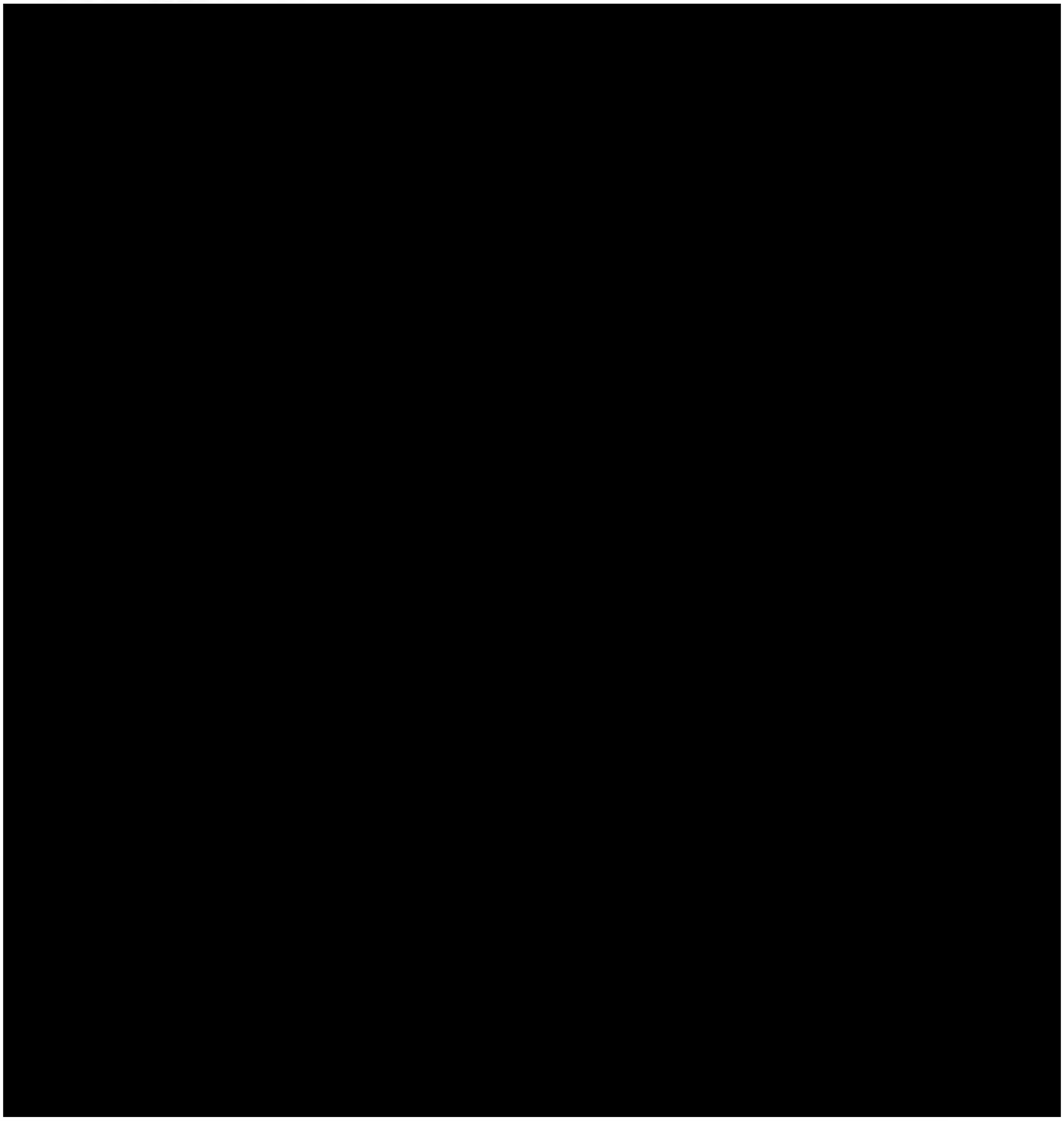
Molecular formula:	$C_{23}H_{22}ClF_3O_2$
Molecular weight	422.9 g.mol^{-1}
Declared concentration:	Minimum 98.0 % w/w
Physical state:	Solid

Content of active ingredient in the five batches (% w/w)

Active ingredient	201410025	201411020	201410031	201410012	201411006	Average	Standard Deviation
Bifenthrin	98.14	98.28	98.41	98.31	98.26	98.28	0.10

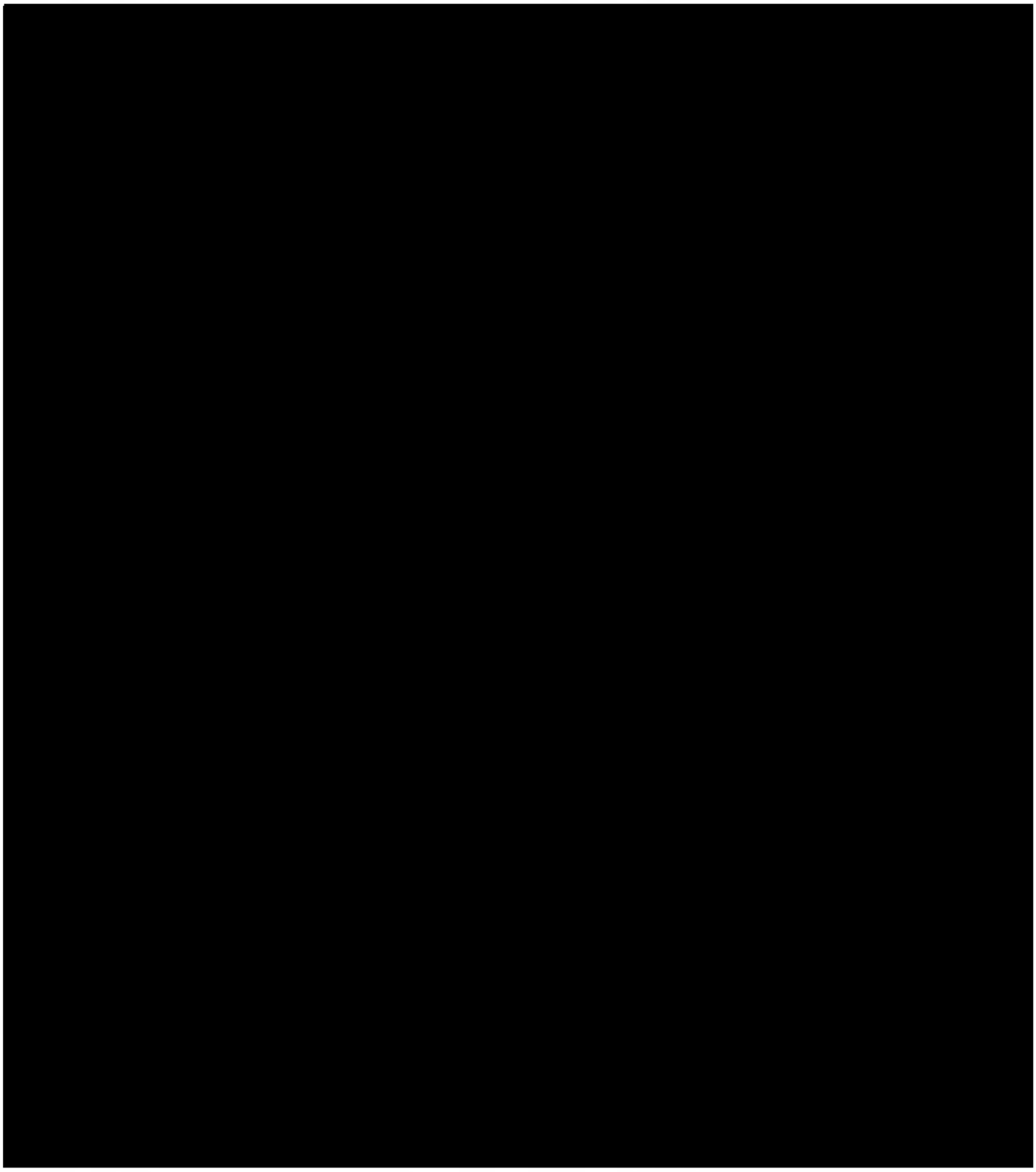
Equipment:	Liquid chromatograph Agilent 1100 series
Detector:	UV
Column:	Eclipse XDB C18 (150 mm x 4.6 mm x 5 µm)
Wavelength:	230 nm
Oven temperature:	40 °C
Flow:	1.0 mL.min^{-1}
Injection volume:	5.0 µL
Run time:	10 minutes
Mobile phase:	Acetonitrile / Ultra pure water (90 : 10 % v/v)

Confidential Appendix

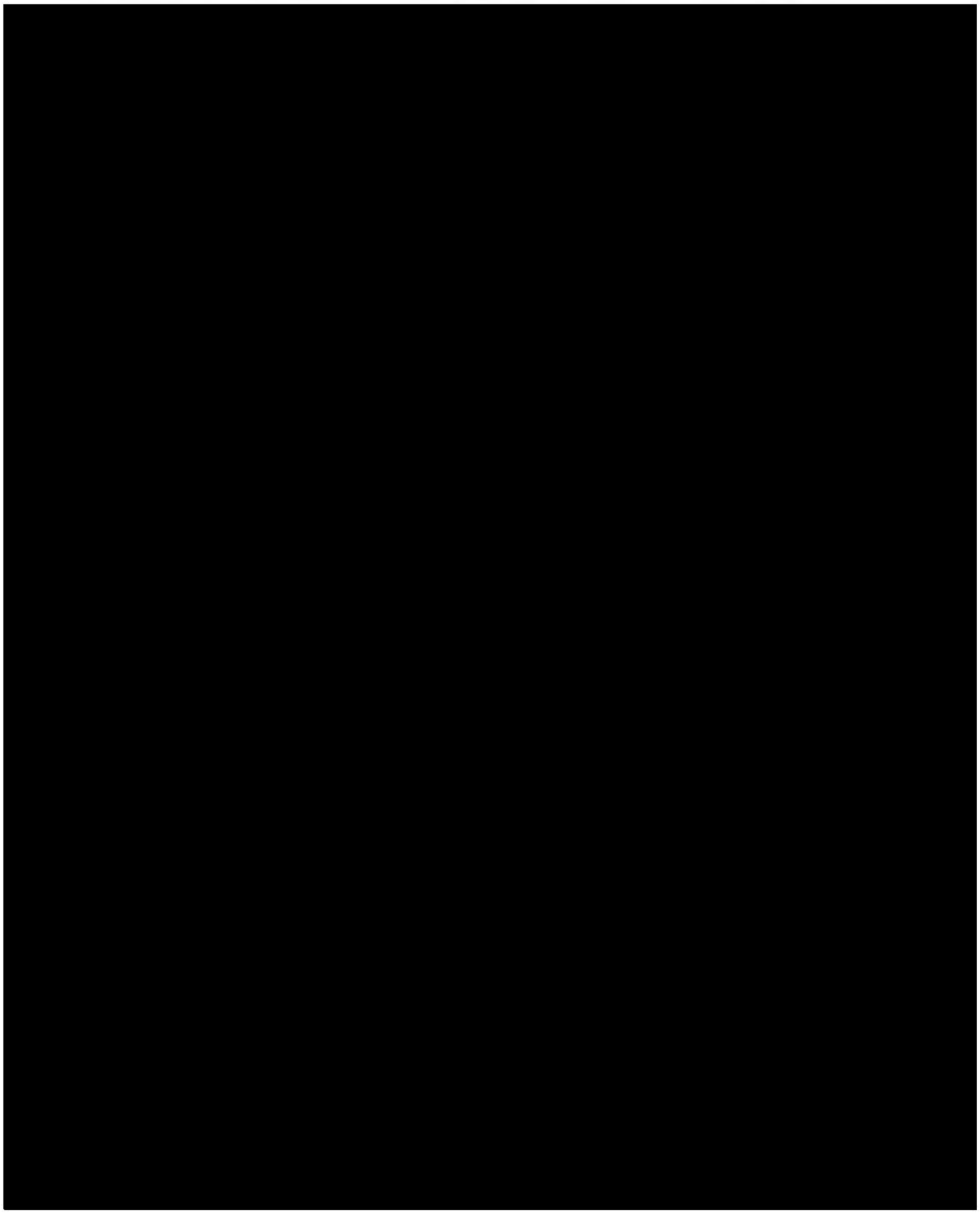


Manufacturing process information may be entitled to confidential treatment

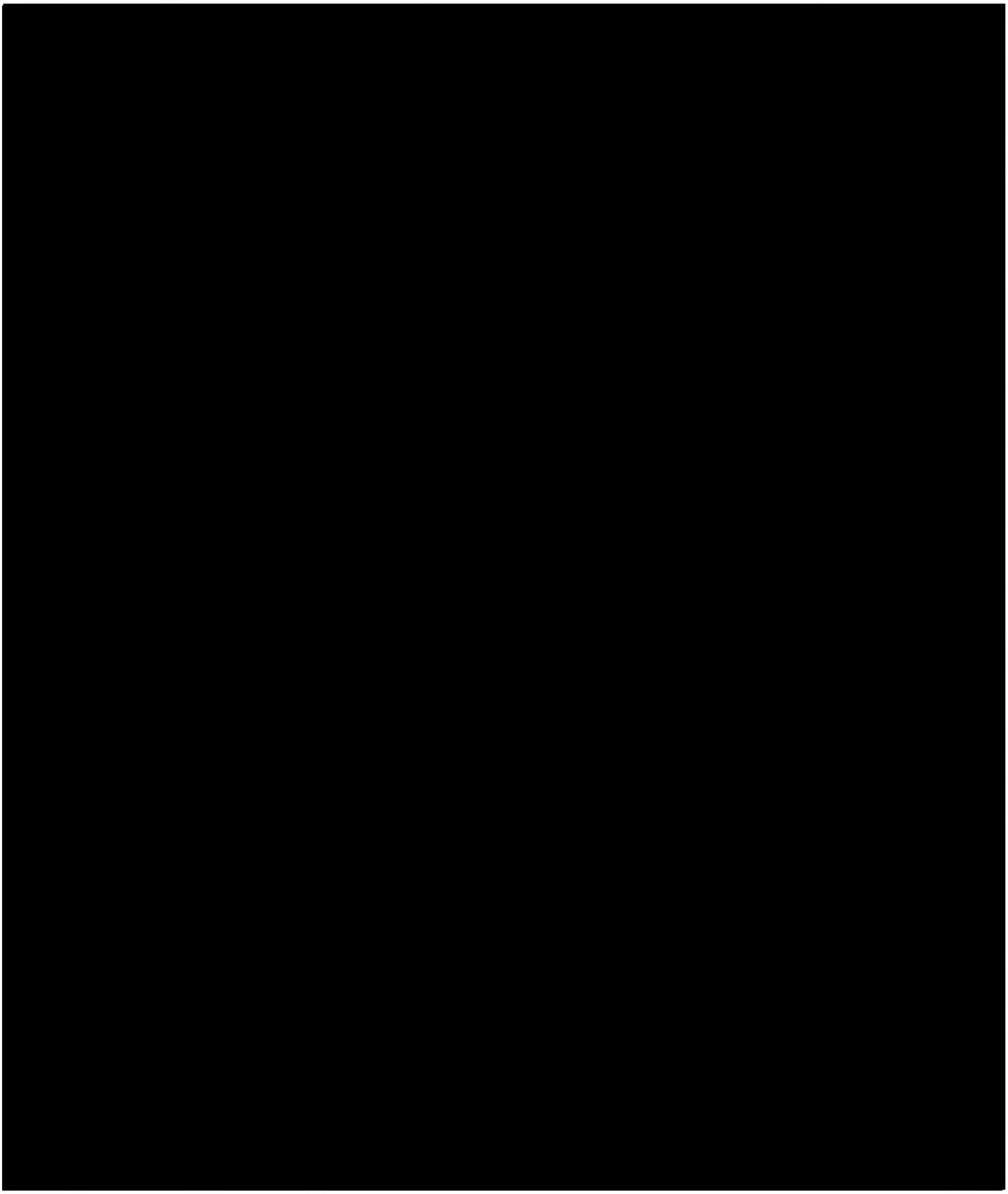
Manufacturing process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment



Manufacturing process information may be entitled to confidential treatment

[redacted]

Pages 11-12 - *Confidential Statements of Formula may be entitled to confidential treatment*